



Multicentre randomised phase III trial comparing Tamoxifen alone or with Transarterial Lipiodol Chemoembolisation for unresectable hepatocellular carcinoma in cirrhotic patients (Fédération Francophone de Cancérologie Digestive 9402)

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The FFCD 9402 multicentre phase III trial was designed to compare the effects of the combination of Transarterial Lipiodol Chemoembolisation (TACE) and tamoxifen with tamoxifen alone on overall survival and quality of life in the palliative treatment of hepatocellular carcinoma with cirrhosis. From 1995 to 2002, 138 patients were randomised between the two groups. One hundred and twenty three patients were eligible including 61 in the Tamoxifen group and 62 in the TACE group. Baseline characteristics were similar: Child-Pugh class A: 70%, alcoholic cirrhosis: 76%, Okuda stage I: 71%, multinodular tumour: 70% and segmental portal vein thrombosis: 10%. At 2 years, the overall survival was 22% and 25% in the Tamoxifen and TACE groups ($P = .68$), respectively. Multivariate analysis identified four independent prognostic factors for survival: α -fetoprotein (AFP) > 400 ng/mL ($P = .008$), abdominal pain ($P = .011$), hepatomegaly ($P = .023$) and Child-Pugh score ($P = .032$). The Spitzer Index level assessing the quality of life during follow-up did not differ between the two groups ($P = .70$). Amongst patients with stage Okuda I, the 2-year overall survival was 28% in the Tamoxifen group and 32% in the TACE group ($P = .58$). In this subgroup, two prognostic factors were statistically significant for survival: AFP > 400 ng/mL ($P = .004$) and Spitzer Index ($P = .013$) as shown by multivariable analysis. In conclusion, this study suggests that TACE improves neither the survival nor the quality of life in patients with HCC and cirrhosis.

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